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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/292,056 04/14/99 GREENBERGER

J PITT-1DIV

HM12/0424

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EXAMINER

SOLAYA, J

ART UNIT

PAPER NUMBER

1655
DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/292,056

Applicant(s)
Greenberger et al

Examiner
Jehanne Souaya

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 9, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 47-123 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1 and 47-123 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 47-50, 94, 96, 103, and 104, drawn to an apparatus for holding a plurality of cells comprising:
 - a mechanism for incubating a plurality of cells which includes wells
 - a mechanism for determining the state of cells
 - an imaging mechanism,classified in class 435, subclass 287.1.
 - II. Claims 57-64 and 70, drawn to an apparatus for growing cells comprising:
 - a mechanism for incubating cells which includes wells
 - a tracking mechanism
 - an identifying mechanism which identifies division and differentiation,classified in class 435, subclass 288.4.
 - III. Claim 74, drawn to an apparatus for holding a stem cell comprising:
 - a mechanism for incubating the cell
 - a mechanism for determining a desired state of the cell
 - a mechanism for introducing media to the cell,classified in class 435, subclass 286.4.

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IV. Claims 75-79, drawn to an apparatus for holding a plurality of cells comprising:

- a mechanism for incubating the plurality of cells
- a controlling mechanism for exchanging media
- a mechanism for determining the state of the cells
- a mechanism for automatically testing fro predetermined biological variables,

classified in class 435, subclass 287.3.

V. Claims 80-81, 86-95, 97, and 99-100, drawn to an apparatus for holding cells comprising:

- a mechanism for incubating the cells
- a robotic arm
- a mechanism for controlling the environment about each cell,

classified in class 436, subclass 286.1.

VI. Claims 51-56, drawn to an apparatus for incubating and determining the state of cells comprising:

- a mechanism for incubating cells
- a mechanism for determining the state of cells
- a mechanism for determining a biological event
- a mechanism for determining a stage of cells based on a metabolic process,

classified in class 435, subclass 287.1.

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VII. Claims 65-69, 73, 82-84, 98, 101, 107, 108, and 110, drawn to an apparatus and method for developing desired processes for control of a cell comprising:

- a mechanism for incubating a plurality of cells
- a robotic arm
- a mechanism for determining which materials enhance a desired process,
- a diagnostic mechanism for ascertaining the occurrence of a biological event
- a determining mechanism which determines how to insert transgenes
- an imaging mechanism

classified in class 435, subclass 286.1 (apparatus) and 435, subclass 375 (method).

VIII. Claims 71-72, 85, 105-106, and 109, drawn to a method for growing cells, classified in class 435, subclass 383.

IX. Claims 114-123, drawn to an apparatus for culturing and analyzing cells comprising:

- a biochamber
- a liquid handling system
- an image recognition system
- a stage for supporting the biochamber
- a system controller
- a microscope,

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classified in class 435, subclass 289.1.

2. The inventions are distinct, each from the other because of the following reasons: The inventions of group VII and groups I-VI and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the apparatus of group VII does not contain the mechanism for determining the state of cells of groups I, III, IV, VI the tracking mechanism of group II, the mechanism for controlling the environment about each cell of group V, the mechanism for determining a stage of cells based on a metabolic process of group VI, the mechanism for automatically testing for predetermined biological variables of group IV, the stage for supporting the biochamber of group IX, or the system controller of group IX. The subcombinations of groups I, IV, V have separate utility such as apparatus for holding cells, the subcombination of group II has separate utility as an apparatus for growing cells, the subcombination of group III has separate utility as an apparatus for holding a single stem cell, the subcombination of group VI has separate utility as an apparatus for incubating and determining the state of cells, the subcombination of group IX has separate utility as an apparatus for culturing and analyzing cells.
3. The inventions of groups I-VI and IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are

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shown to be separately usable. In the instant case, the invention of group II has separate utility such as an apparatus for growing cells, the invention of group III has separate utility such as an apparatus for holding a single stem cell, the invention of group VI has separate utility such as an apparatus for determining the state of cells, the invention of group IX has separate utility as such as an apparatus for culturing and analyzing cells. Although the inventions of groups I, IV and V are all drawn to apparatus for holding cells, each apparatus contain features which confer separate utility to each apparatus. The apparatus of group V contains the limitation of a mechanism for controlling the environment about each cell, whereas the apparatus of groups I and IV are not drawn to such a limitation. The apparatus of group IV contains the limitations of a controlling mechanism for exchanging media and mechanisms for automatically teasing for predetermined biological events, whereas the apparatus of groups I and V are not drawn to such limitations. See MPEP § 806.05(d).

4. The invention of groups II and VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of group VIII does not require the imaging mechanism of group II, therefore, the apparatus required to practice the invention of group VIII is different from the apparatus of group II. Furthermore, the apparatus of group II can be used to image cells.

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5. The inventions of groups I, III-VII and IX and the invention of group VIII are patentably distinct as the apparatus of groups I, III-VII and IX are not needed to practice the invention of group II. Specifically, the apparatus of group I contains an imaging mechanism which is not required to practice the method of group VIII. The apparatus of groups III, IV, and VI contain a mechanism to determine the state of cells which is not required to practice the method of group VIII. The apparatus of groups V and VII contain a robotic arm which is not required to practice the invention group VIII. Such steps in the method of group VIII can be practiced by hand. The apparatus of group IX contains a stage for supporting the biochamber and a system controller which are not required to practice the method of group VIII.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IX, restriction for examination purposes as indicated is proper.

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9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
11. Applicant should note that claims 102 and 111-113 have not been addressed in the above restriction. These claims are dependent on canceled claims.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner

Jehanne Souaya
April 23, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600